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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,700	BONENBERGER ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed February 20, 2008. Claims 1, 3 and 12 were amended. Applicant's amendments requiring the presence of the analyte in the sample will reduce the signal produced by binding of the macromolecule bound analyte to the capture molecule coupled to the solid carrier necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

2. Claims 1-17 are pending in this application.

3. Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of group II there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 5, 2007.

4. Claims 1-10, 12-17 are under prosecution.

Note

5. The claim listing includes the withdrawn claim 11, which was drawn to a nonelected invention of group II, without proper identifier. The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following status identifiers: (original), (currently amended), (previously presented), (canceled), (withdrawn), (new), or (not entered). The status identifier (withdrawn– currently amended) is also acceptable for a withdrawn claim that is being currently amended (MPEP, 37 CFR 1.121, section c).

Amendments to Claims

6. Amendments to the claims 1, 3 and 12 have been reviewed and entered.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 7, 9-10, 14 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Zoha et al (USPN 5,300,423 issued April 5, 1994).

Regarding claim 1, Zoha et al teaches a competitive binding assay for detecting analytes that includes incubating a sample with latex particles (Fig. 3b, # 54) to each of which at least two molecules of the analyte to be detected in the sample are coupled (Fig. 3b, See at least three analytes # 52 on the particle, column 6, lines 3-9, step 'a' of the claim). The latex particles of Zoha et al are macromolecules of the instant claim.

Zoha et al also teaches that the inner wall of the cuvette, i.e., solid carrier bears the binding partner for the analyte (Fig. 3, Wall # 29, Fig. 3b, Binding partner for the analyte # 50, Analyte # 52, column 6, lines 6-8). Zoha et al also teaches incubating the sample with solid carrier and further teaches that in the absence of the analyte in the sample, the particles bearing the analyte bind extensively to the solid carrier, whereas the presence of the analyte inhibits the binding of particles (Fig. 3b, column 6, lines 9-13, step 'b' of the claim).

Zoha et al also teaches that the latex particles are coated with fluorescent dye (column 6, lines 37-40) thus teaching staining of macromolecules with fluorescent dye (step 'c' of the claim. Zoha et al further teaches that the high concentration of analytes in the sample results in lower extent and rate of binding of fluorescent particles to the binding partners on the solid carrier, whereas in the absence of the analyte in the sample, the fluorescent particles bearing the analyte bind extensively to the solid carrier (column 6, lines 3-15) thus teaching detecting the analytes present in the sample by excitation of the fluorescence dye, wherein the presence of analyte in the sample will reduce the signal produced by binding of the macromolecule-bound analyte to the capture molecule coupled to the solid carrier (step 'd' of the claim).

Regarding claim 3, Zoha et al teaches a competitive binding assay for detecting analytes that includes incubating a sample with fluorescence dye marked latex particles (Fig. 3b, # 54) to each of which at least two molecules of the analyte to be detected in the sample are coupled (Fig. 3b, See at least three analytes # 52 on the particle, column 6, lines 3-9 and 37-40, step 'a' of the claim). The latex particles of Zoha et al are macromolecules of the instant claim.

Zoha et al also teaches that the inner wall of the cuvette, i.e., solid carrier bears the binding partner for the analyte (Fig. 3, Wall # 29, Fig. 3b, Binding partner for the analyte # 50, Analyte # 52, column 6, lines 6-8). Zoha et al also teaches incubating the sample with solid carrier and further teaches that in the absence of the analyte in the sample, the particles bearing the analyte bind extensively to the solid carrier, whereas

the presence of the analyte inhibits the binding of particles (Fig. 3b, column 6, lines 9-13, step 'b' of the claim).

Zoha et al further teaches that the high concentration of analytes in the sample results in lower extent and rate of binding of fluorescent particles to the binding partners on the solid carrier, whereas in the absence of the analyte in the sample, the fluorescent particles bearing the analyte bind extensively to the solid carrier (column 6, lines 3-15) thus teaching detecting the analytes present in the sample by excitation of the fluorescence dye, wherein the presence of analyte in the sample will reduce the signal produced by binding of the macromolecule-bound analyte to the capture molecule coupled to the solid carrier (step 'c' of the claim).

Regarding claims 7 and 14, Zoha et al teaches that the latex particles, i.e., macromolecules detect a specific analyte (column 6, lines 3-15), thus teaching macromolecules are identical.

Regarding claims 9 and 16, Zoha et al teaches that the fluorescence dye is a fluorophore (column 6, lines 37-38).

Regarding claims 10 and 17, Zoha et al teaches that the solid carrier (Fig. 3b, # 29) is permeable to light and the detection method is implemented by means of a transmitted-light method (column 5, lines 16-17 and 55-67, column 6, lines 1-2, column 7, lines).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4, 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoha et al (USPN 5,300,423 issued April 5, 1994) in view of Schobell et al (Fresenius J. Anal. Chem., 2000, 366, 646-658).

Claims 8 and 15 are further evidenced by Cameo Chemicals chemical data sheet.

Claims 2 and 8 are dependent from claim 1 and claims 4 and 15 are dependent from claim 3. Teachings of Zoha et al regarding claims 1 and 3 are described in this office action in section 8.

Regarding claims 2 and 4, Zoha et al teaches washing the latex particles in a sandwich assay (Example, column 10, lines 39-41), but are silent about washing step in a competitive binding assay to remove the non-bound latex particles, i.e., macromolecules. However, a washing step to remove the unbound macromolecules was known in the art at the time of the claimed invention was made as taught by Schobell et al who teaches competitive type immunoassay, wherein after the analytes captured on the solid support are washed to separate bound samples from the free samples by one or more washing steps (pg. 648, column 2, paragraph 2).

Regarding claims 8 and 15, Schobell et al teaches low molecular weight analytes comprising 2, 4, dichlorophenoxy acetic acid (Table 3, 2, 4-D) which has a molecular weight of about 221 Daltons, which is less than 5000 Daltons as claimed. It is noted that the molecular weight of 2, 4-D is further evidenced by chemical data sheet for 2, 4-D (Cameo chemicals data sheet).

Schobell also teaches that washing step, i.e., removal of the free samples not bound to the solid carrier reduces the endogenous background fluorescence signal (pg. 648, column 2, paragraph 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the analyte detection method of Zoha et al and include the washing step of Schobell et al with the expected benefit of reducing the endogenous background fluorescence signal as taught by Schobell et al (pg. 648, column 2, paragraph 2).

12. Claims 1-4, 6, 8, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoha et al (USPN 5,300,423 issued April 5, 1994) in view of Cros et al (USPN 5,849,480 issued Dec. 15, 1998).

Claims 2, 6 and 8 are dependent from claim 1 and claims 4, 13 and 15 are dependent from claim 3. Teachings of Zoha et al regarding claims 1 and 3 are described in this office action in section 8.

Regarding claims 2 and 4, Zoha et al teaches washing the latex particles in a sandwich assays (Example, column 10, lines 39-41), but are silent about washing step in a competitive binding assay to remove the non-bound latex particles, i.e., macromolecules. However, a washing step to remove the unbound macromolecules was known in the art at the time of the claimed invention was made as taught by Cros et al who teaches competitive type immunoassay, wherein after the analytes captured on the solid support are rinsed three time with PBS (Example 2, column 10, lines 50-54), thus teaching removal of the unbound macromolecules from the solid carrier.

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the analyte detection method of Zoha et al and include the washing step of Cros et al with the expected benefit of removing the non-bound macromolecules from the solid carrier to obtain highly reproducible results as taught by Cros et al (Table 5).

Regarding claims 6 and 13, Zoha et al teaches latex particle, i.e., macromolecules, bearing analytes (column 6, lines 6-8) but are silent about macromolecules are single stranded oligonucleotides. However, macromolecules

containing single stranded oligonucleotides were known in the art at the time of the claimed invention was made as taught by Cros et al who teaches competitive type immunoassay, wherein the hapten is conjugated to solid support with single stranded nucleic acids (column 2, lines 46-54, column 3, lines 1-4). Cros et al further teaches single stranded nucleic acids comprise 2 to 100 nucleotides, which is within the range as claimed (column 3, lines 5-7). Cros et al also teaches conjugation of nucleic acids prevents intramolecular reorganization of the haptens, which introduces significant errors in the accuracy of the test (column 1, lines 35-60).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the method of hapten attachment to the latex particles of Zoha et al and use the single stranded oligonucleotide method of Cros et al with a reasonable expectation of success.

An artisan would have been motivated to modify the method of hapten attachment to the latex particles of Zoha et al and use the single stranded oligonucleotide method of Cros et al with the expected benefit of preventing intramolecular reorganization of the haptens, which introduces significant errors in the accuracy of the test as taught by Cros et al (column 1, lines 35-60), thus improving the accuracy of the test in the competitive binding assay of Zoha et al.

Regarding claims 8 and 15, Zoha et al teaches macromolecules are nucleic acids, antigens, hormones and receptors, lectins and sugars (column 5, lines 60-62 and column 6, lines 3-6), but are silent about molecular weight. However, low molecular analyte detection was known in the art at the time of the claimed invention was made as

taught by Cros et al who teaches competitive type immunoassay, wherein the analytes include ADP, ATP, vitamins including biotin, estradiol and medical products (column 2, lines 12-38), thus teaching analytes, (i.e., ADP, ATP, Biotin) having molecular weight less than 5000 Daltons. Cros et al also teaches the detection of testosterone and estradiaol (Examples 2 and 3).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the analyte detection method of Zoha et al and include the low molecular analyte detection method of Cros et al with the expected benefit of expanding the repertoire of analyte detection in the method of Cros et al.

13. Claims 1, 3, 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoha et al (USPN 5,300,423 issued April 5, 1994) in view of Nilsen et al (USPN 5,175,270 issued Dec. 29, 1992).

Claim 5 is dependent from claim 1 and claim 12 is dependent from claim 3. Teachings of Zoha et al regarding claims 1 and 3 are described in this office action in section 8.

Regarding claims 5 and 12, Zoha et al teaches that the macromolecules are latex particles (column 5, lines 60-62 and column 6, lines 3-6) but silent about macromolecules are nucleic acids, peptide nucleic acids, polyaminoacids. However, macromolecules comprising nucleic acids were known in the art at the time of the claimed invention was made as taught by Nilsen et al who teaches novel class of reagents for detecting target nucleic acid reagents comprising nucleic acid attached to

the bead, i. e., macromolecule (Fig. 6, column 15, lines 66-67), thus teaching macromolecules are nucleic acids. Nilsen et al further teaches that the beads containing nucleic acids allows detection of targets at variety of concentration with less background (column 17, lines 62-67, column 18, lines 19-32).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the analyte detection method of Zoha et al and include the nucleic acid containing macromolecules of Nilsen et al with the expected benefit of detecting targets at variety of concentration with less background as taught by Nilsen et al (column 17, lines 62-67, column 18, lines 19-32).

Response to Remarks from the Applicants

Claim Rejections under 35 U.S.C. § 102(b)

14. Applicant's arguments with respect to claims 10-12 and 15 have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 1-3).

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

Narayan K. Bhat Ph. D.

/BJ Forman/

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